MEDSIR's PRIMED Study Shows Promising Results for Preventing Breast Cancer Drug Sacituzumab Govitecan Side Effects

In addition to PRIMED, the MEDSIR and Oncoclínicas strategic alliance has enabled the company to present 12 other studies at the 2024 ASCO Annual Meeting.

MEDSIR

CHICAGO, ILLINOIS, USA, June 3, 2024 /EINPresswire.com/ -- Leading international medical research company, MEDSIR, today announced the results of the recent PRIMED clinical trial during the 2024 ASCO Annual Meeting. Carried out under the company's collaborative model, this Investigator-Initiated Trial (IIT) demonstrated the effectiveness of preventative administration of drugs to treat the common side effects of neutropenia and diarrhea that can occur while taking sacituzumab govitecan, an antibody-drug conjugate targeting Trop-2 that has extended overall survival for patients with pretreated triple negative and HR-positive/HER2-negative advanced breast cancer in two previous Phase 3 studies, ASCENT and TROPiCS-02. In the PRIMED study, adding primary prophylactic granulocyte colony-stimulating growth factors (G-CSF) and loperamide during the first two sacituzumab govitecan treatment cycles led to clinically meaningful reductions in neutropenia and diarrhea, lowering the need for dose reductions, treatment interruptions, and permanent discontinuations.

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> *Dr. Antonio Llombart-Cussac, Senior Scientific Leader of MEDSIR*

"This is an exciting finding that highlights the high potential of prophylactic strategies that can mitigate side effects to help keep patients on promising treatments, which was made possible by our collaborative research model," shared Dr. Antonio Llombart-Cussac, Senior Scientific Leader of MEDSIR. "By using a partnership model that combines the benefits of company-sponsored research with all the advantages of IITs, we are turning brilliant ideas into full clinical trials that will safely and efficiently advance cancer solutions. It is our hope that, by working together, we will continue to generate new opportunities for patients worldwide."

Among PRIMED study participants, the incidence of any grade of neutropenia (in the first two cycles) was 28%, compared to 63% and 70% in ASCENT and TROPiCS-02 (in the full study), respectively. The incidence of any grade diarrhea (in the first two cycles) was 34%, compared to 59% and 57% in ASCENT and TROPiCS-02 (in the full study), respectively. The other side effects PRIMED study participants experienced were consistent to the known safety profile of sacituzumab govitecan, with the exception of constipation, which occurred in 46% of patients during the first two cycles compared to 17% in ASCENT and 19% in TROPiC-02 (in the full study). However, most cases of constipation were mild, and no patients experienced adverse events that led to permanent treatment discontinuation.

The study, which is still ongoing to evaluate efficacy and collect longer-term safety data, enrolled 50 patients between February 2023 and September 2023 across 10 sites across Spain, providing them with G-CSF and loperamide during the first two sacituzumab govitecan treatment cycles (physician's decision to continue after two cycles). These two drugs are commonly used to treat neutropenia and diarrhea, respectively, but are usually administered only after these side effects occur. In PRIMED, researchers wanted to test whether early administration of these drugs, before patients experienced any neutropenia or diarrhea, could reduce the incidence of these side effects and determine how this affected the need for dose reductions, treatment interruptions, and permanent discontinuations.

Showcasing Numerous Promising Collaborative Trials at ASCO

PRIMED was not the only trial MEDSIR presented during the ASCO Annual Meeting. It shared the results of several other recent and ongoing studies as well.

Recently published in The Lancet, MEDSIR's PHERGain phase II trial (NCT03161353) demonstrated how a third of patients with HER2-positive early breast cancer could be safely treated without using chemotherapy. At the 2024 ASCO Annual Meeting, MEDSIR presented a subanalysis of this study comparing PET scan and magnetic resonance imaging (MRI) results; both tests that participants undergo to observe the evolution of their cancer. The comparative study shows tumor assessments can be analyzed with both PET scan and MRI. Although PET scan is the recommended imaging technique for early treatment response, this exploratory study suggests that MRI could alternatively guide the treatment when PET scan are not available.

MEDSIR's PATHFINDER study evaluated the safety, tolerability, and preliminary efficacy of ipatasertib in combination with non-taxane chemotherapy in patients with advanced triple negative breast cancer who had previously experienced tumor progression after treatment with taxane chemotherapy. Study results revealed that combining ipatasertib with capecitabine and eribulin has an acceptable safety profile in these patients, but that adding ipatasertib alongside carboplatin plus gemcitabine proved to be intolerable. Additionally, the combination of ipatasertib and eribulin demonstrated encouraging efficacy, warranting further investigation.

TUXEDO-3, one of MEDSIR's ongoing clinical trials in Austria and Spain, is the first study evaluating the efficacy and safety of patritumab deruxtecan as an anti-cancer therapy for patients with pretreated metastatic breast cancer and advanced non-small cell lung cancer with brain metastases, and metastatic solid tumors with leptomeningeal disease. If positive, this study could streamline the introduction of HER3-DXd as a new treatment for these patients who currently have very limited therapeutic options.

ABOUT UMMET CANCER NEEDS

Unmet cancer needs refer to gaps in resources, support, and treatment options that exist for cancer patients. Addressing unmet cancer needs is crucial to improving quality of life and outcomes for cancer patients. Through the collaborative work of healthcare providers, policymakers, and patient advocacy groups unmet cancer needs can be identified to help provide patients with comprehensive and quality care.

ABOUT MEDSIR

Founded in 2012, MEDSIR works closely with its partners to drive innovation in oncology research. Based in Spain and the United States, the company manages all aspects of clinical trials, from study design to publication, utilizing a global network of experts and integrated technology to streamline the process.

The company offers proof-of-concept support and a strategic approach that helps research partners experience the best of both worlds from industry-based clinical research and investigator-driven trials. To promote independent cancer research worldwide, MEDSIR has a strategic alliance with Oncoclínicas, the leading oncology group in Brazil with the greatest research potential in South America. Learn how MEDSIR brings ideas to life at www.medsir.org.

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